IN THE CLAIMS:

In accord with Rule § 1.121, a complete claim listing is presented below, including appropriate status identifiers. The changes in amended claims are shown by strikethrough or double brackets for deleted material, and by underlining for added material.

1. (Currently Amended) A sterile pharmaceutical composition of propofol in a container, comprising:

a container which includes a closure ~~inert to propofol~~ and a composition in the container,

the composition in the container comprising from 0.5% to 10% by weight propofol and less than ~~about~~ 10% by weight solvent for propofol, and

when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol.

2. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, the composition further comprising an aqueous phase and protein.

3. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the protein is albumin.

4. (Previously presented) The sterile pharmaceutical composition in a container according to claim 3, wherein the albumin is present in an amount of from about 0.01% to about 5% by weight of the composition.

5. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the aqueous phase comprises water for injection and a pH modifier.

6. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the composition comprises a tonicity agent.

7. (Previously presented) The sterile pharmaceutical composition in a container according to claim 3, wherein the pH modifier is sodium hydroxide.

8. (Previously presented) The sterile pharmaceutical composition in a container according to claim 6, wherein the tonicity agent is glycerin.

9. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the composition further comprises a surfactant.

10. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition further comprises a solvent for propofol.

11. (Previously presented) The sterile pharmaceutical composition in a container according to claim 10 wherein the solvent is a water-immiscible solvent.

12. (Previously presented) The sterile pharmaceutical composition in a container according to claim 11, wherein the water-immiscible solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glyceral ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof.

13. (Previously presented) The sterile pharmaceutical composition in a container according to claim 12, wherein the water-immiscible solvent is soybean oil.

14. (Previously presented) The sterile pharmaceutical composition in a container according to claim 10, wherein the solvent is selected from the group consisting of chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane,

acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

15. (Previously presented) The sterile pharmaceutical composition in a container according to claim 9, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids, natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block co-polymers, polyvinyl pyrrolidone, and polyvinylalcohol and combinations thereof.

16. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 15, wherein the surfactant is selected from the group consisting of egg phosphatides, soya phosphatides, egg lecithins, soya lecithins, and ~~compositions~~ combinations thereof.

17. (Previously presented) The sterile pharmaceutical composition in a container according to claim 16, wherein the surfactant is egg lecithin.

18. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure is coated with a material inert to propofol.

19. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure ~~is comprised~~ consists essentially of a material that is itself inert to propofol.

20. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 19, wherein the closure material ~~inert to propofol~~ is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

21. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 19, wherein the closure material is a non-rubber selected from the group consisting of ~~bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber,~~ metal, plastics, and mixtures thereof.

22. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~19~~ 1, wherein the closure comprises a material ~~is~~ selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

23. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

24. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized bromobutyl rubber.

25. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises a non-rubber~~, or~~ selected from the group consisting of metal, plastics, and mixtures thereof.

26. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

27. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized chlorobutyl rubber.

28. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition comprises ~~propofol in an amount of from about 0.1% to about 10% by weight of the composition,~~ soybean oil in an amount of from

about 0.5% to about 6% by weight of the composition, egg lecithin in an amount of from about 0.1% to about 5% by weight of the composition and human serum albumin in an amount of from about 0.1% to about 5% of the composition.

29. (Currently Amended) A sterile pharmaceutical composition of propofol in a container, comprising:

a container which includes a closure ~~inert to propofol~~ and an oil-in-water emulsion for parenteral administration of propofol in the container,

the ~~composition~~ emulsion comprising an oil phase comprising propofol and ~~less than about 10% by weight~~ a solvent for propofol, and an aqueous phase comprising water for injection,

the emulsion comprising less than 10% by weight of the solvent, ~~and~~

the ~~composition~~ emulsion further comprising a stabilizing layer for the oil phase, the stabilizing layer comprising a surfactant and a protein;

where when the emulsion in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the emulsion maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol.

30. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the protein is selected from the group consisting of albumins, globulins, immunoglobulins, lipoproteins, caseins, insulins, hemoglobins, lysozymes, alpha-2-macroglobulin, fibronectins, vitronectins, fibrinogens, lipases, peptides, enzymes, antibodies and combinations thereof.

31. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids, natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block co-polymers, polyvinyl pyrrolidone, and polyvinylalcohol.

32. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the oil phase is propofol neat.

33. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the surfactant is lecithin and the protein is albumin.

34. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the oil phase includes a solvent, and wherein the solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glyceral ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof, chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane, acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

35. (Previously presented) The sterile pharmaceutical composition in a container according to claim 34, wherein the solvent is soybean oil.

36. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 35, wherein the soybean oil is present in an amount of from about 0.5% to about 6% by weight of the ~~composition~~ emulsion.

37. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 33, wherein the egg lecithin is present in the ~~composition~~ emulsion in an amount of from about 0.1% to about 5% by weight of the ~~composition~~ emulsion and the albumin is present in the ~~composition~~ emulsion in an amount of from about 0.01% to about 5% by weight of the ~~composition~~ emulsion.

38. (Previously presented) The sterile pharmaceutical composition in a container according to claim 37, wherein the oil phase includes soybean oil.

39. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 38, wherein the soybean oil is present in an amount of from about 0.5% to about 6% by weight of the ~~composition~~ emulsion.

40. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 38, wherein the soybean oil is present in the ~~composition~~ emulsion in an amount of from about 0.5% to about 3% by weight of the ~~composition~~ emulsion.

41. (Previously presented) The sterile pharmaceutical composition in a container according to claim 31, comprising:

a) about 1% to 2% by weight of propofol,
b) 3-6% by weight of soybean oil,
c) 0.2-1.0% by weight of egg lecithin,
d) about 2.25% by weight of glycerin,
e) sodium hydroxide,
f) water to 100%, and
g) pH between 5.0-8.5.

42. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure is treated with a material inert to propofol.

43. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure ~~comprises~~ consists essentially of a material that is itself inert to propofol.

44. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~42~~ 43, wherein the closure material ~~inert to propofol~~ is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

45. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 43, wherein the closure material is a non-rubber selected from the group consisting of ~~bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber,~~ metal, plastics, and mixtures thereof.

46. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~46~~ 29, wherein the closure comprises a material ~~is~~ selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

47. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

48. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises siliconized bromobutyl rubber.

49. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises a non-rubber~~, or~~ selected from the group consisting of metal, plastics, and mixtures thereof.

50. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

51. (Previously presented) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises siliconized chlorobutyl rubber.

52. (Currently Amended) A sterile, injectable pharmaceutical composition in a container, comprising:

a container which includes a closure ~~inert to propofol~~ and a composition in the container, the composition comprising:

a) microdroplets having a mean size of from about 20 nanometers to about 1000 nanometers, the microdroplets comprising a sphere of propofol surrounded by a stabilizing layer comprising a phospholipid and devoid of oils capable of supporting bacterial growth; and

b) a pharmaceutically acceptable injectable carrier;

where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol.

53. (Previously presented) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the composition further comprises albumin.

54. (Previously presented) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the stabilizing layer includes albumin.

55. (Previously presented) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure is coated with a material inert to propofol.

56. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure ~~comprises~~ consists essentially of a material that is itself inert to propofol.

57. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim ~~55~~ 56, wherein the closure material ~~inert to propofol~~ is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

58. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim 56, wherein the closure material is a non-rubber selected from the group consisting of ~~bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber,~~ metal, plastics, and mixtures thereof.

59. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim ~~55~~ 52, wherein the closure comprises a material ~~is~~ selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

60. (Previously presented) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

61. (Previously presented) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure comprises siliconized bromobutyl rubber.

62. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure comprises a non-rubber~~, or~~ selected from the group consisting of metal, plastics and mixtures thereof.

63. (Previously presented) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

64. (Previously presented) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure comprises siliconized chlorobutyl rubber.

65-67. (Cancelled)

68. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein ~~the concentration of propofol in~~ when the composition is stored in the container sealed with the closure for at least two months, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least about 95% of the starting concentration (w/v) of the propofol ~~for at least about two months~~.

69. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 68, wherein the composition is stored in the container sealed with the closure in a controlled environment of about 40°C and about 75% relative humidity for at least ~~about~~ two months.

70. (Cancelled)

71. (New) The sterile pharmaceutical composition in a container according to claim 1, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 95% of the starting concentration (w/v) of the propofol.

72. (New) The sterile pharmaceutical composition in a container according to claim 1, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 97% of the starting concentration (w/v) of the propofol.

73. (New) The sterile pharmaceutical composition in a container according to claim 1, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 99% of the starting concentration (w/v) of the propofol.

74. (New) The sterile pharmaceutical composition in a container according to claim 29, where when the emulsion in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the emulsion maintains a propofol concentration (w/v) measured by HPLC that is at least 95% of the starting concentration (w/v) of the propofol.

75. (New) The sterile pharmaceutical composition in a container according to claim 29, where when the emulsion in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the emulsion maintains a propofol concentration (w/v) measured by HPLC that is at least 97% of the starting concentration (w/v) of the propofol.

76. (New) The sterile pharmaceutical composition in a container according to claim 29, where when the emulsion in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the emulsion maintains a propofol concentration (w/v) measured by HPLC that is at least 99% of the starting concentration (w/v) of the propofol.

77. (New) The sterile pharmaceutical composition in a container according to claim 29, where when the emulsion is stored in the container sealed with the closure for at least two months, the emulsion maintains a propofol concentration (w/v) measured by HPLC that is at least 95% of the starting concentration (w/v) of the propofol.

78. (New) The sterile pharmaceutical composition in a container according to claim 29, where when the emulsion is stored in the container sealed with the closure in a controlled environment of about 40°C and about 75% relative humidity for at least two months, the emulsion maintains a propofol concentration (w/v) measured by HPLC that is at least 95% of the starting concentration (w/v) of the propofol.

79. (New) The sterile, injectable pharmaceutical composition in a container according to claim 52, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 95% of the starting concentration (w/v) of the propofol.

80. (New) The sterile, injectable pharmaceutical composition in a container according to claim 52, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 97% of the starting concentration (w/v) of the propofol.

81. (New) The sterile, injectable pharmaceutical composition in a container according to claim 52, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 99% of the starting concentration (w/v) of the propofol.

82. (New) The sterile, injectable pharmaceutical composition in a container according to claim 52, where when the composition is stored in the container sealed with the closure for at least two months, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 95% of the starting concentration (w/v) of the propofol.

83. (New) The sterile, injectable pharmaceutical composition in a container according to claim 52, where when the composition is stored in the container sealed with the closure in a controlled environment of about 40°C and about 75% relative humidity for at least two months, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 95% of the starting concentration (w/v) of the propofol.

84. (New) The sterile pharmaceutical composition in a container according to claim 1, the composition comprising less than about 0.5% by weight solvent for propofol, and the closure comprises a material selected from the group consisting of a fluoropolymer, a metal, and butyl rubber coated with a fluoropolymer.

85. (New) The sterile pharmaceutical composition in a container according to claim 1, the composition comprising from about 0.5% to about 6% by weight solvent for propofol, and the closure comprises a material selected from the group consisting of a fluoropolymer, a metal, butyl rubber coated with a fluoropolymer, bromobutyl rubber and chlorobutyl rubber.

86. (New) The sterile pharmaceutical composition in a container according to claim 86, the composition comprising from about 3% to about 6% by weight solvent for propofol.

87. (New) The sterile pharmaceutical composition in a container according to claim 86, the solvent comprising soybean oil.

88. (New) The sterile pharmaceutical composition in a container according to claim 28, wherein the closure comprises a material selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, metal, and combinations thereof.